RECOVERY OF MICROVASCULAR MYOCARDIAL RESISTANCE AFTER ST ELEVATION MYOCARDIAL INFARCTION AND ITS RELATION TO OUTCOME

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1) To evaluate changes in microvascular resistance of the infarcted area in the first hours after ST-elevation myocardial infarction and during the recovery period (

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON44383

Source
ToetsingOnline

Brief title
microvascular resistance STEMI study

Condition

- Coronary artery disorders

Synonym
acute myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: er Is geen extra financiering

Intervention

Keyword: absolute flow, magnetic resonance imaging (MRI), microvascular resistance, ST-elevation myocardial infarction (STEMI)

Outcome measures

Primary outcome

evaluate changes in myocardial resistance over time in STEMI patients, both in

the early stage and the subacute phase. It is hypothesized that patients can be

divided into 3 groups:

A. Patients with an (almost) normal resistance and flow immediately after PPCI

B. Patients with still elevated resistance and decreased flow immediately after

PPCI, but (partial) recovery in the next days

C. Patients with elevated resistance and decreased flow immediately after PPCI

which do not recover at all.

Secondary outcome

The course of such changes and recovery of the microcirculation will be

correlated to long-term outcome as assessed by MRI measurements and final

infarct size

1) Long term outcome

2) final infarct size on MRI

Study description

Background summary

In acute myocardial infarction, early restoration of blood flow to the

jeopardized myocardium is of paramount importance to limit infarct size and to improve long term outcome. Primary percutaneous coronary intervention (PPCI) is the treatment of choice in these patients1. Despite achievement of adequate epicardial coronary artery reperfusion in many patients, transient or persistent myocardial microvascular dysfunction is often present, also referred to as the no-reflow phenomenon. This microvascular dysfunction and the time course during which it recovers, is most likely also related to long term outcome.If microvascular reperfusion is still limited immediately after myocardial infarction but recovers quickly in the days thereafter, this might be beneficial for long term prognosis. Several treatments have been suggested to limit microvascular injury and to improve microvascular reperfusion in the acute phase of myocardial infarction (such as intra aortic balloon pumping, glycoprotein IIB/IIIA inhibitors, adenosine, verapamil, nitroglycerine, cyclosporine, or gap-junction-inhibitors), but it has been difficult to assess the effect of such treatment due to the simple fact that no methodology has been available for quantitative assessment of the microcirculation of the heart.

Assessment of microvascular perfusion and function has been very difficult so far and has been hampered by a number of methodological and technical shortcomings. Recently, measurement of absolute blood flow in the infarcted area and true quantitative calculation of absolute resistance in acute myocardial infarction, has been performed in a small group of patients using a technique with thermodilution and continuous infusion of small amounts of saline. Technical performance of such measurements was difficult so far because of a complex instrumentation and the necessity of additional administration of intravenous adenosine. Recently, this technique has been largely simplified by the introduction of a new multipurpose monorail infusion catheter (RayFlow®, Hexacath, Paris) and the observation that saline infusion of 15-20 ml/min in itself already ensures maximum coronary hyperemia. Finally, easy to handle software has been developed for online interpretation of such measurements. Consequently, measurement of absolute blood flow and myocardial resistance has become easy to perform now and the complete measurements only take a few minutes in addition to a regular PCI or FFR measurement. The measurements are absolutely safe, reproducible, only a small amount of saline (100 ml at room temperature) is needed, no additional medication is necessary, the patient doesn*t experience any discomfort of the measurement and the measurements can be repeated multiple times within minutes. Therefore, a window is opened for further examination and quantitative assessment of the microcirculation of the heart. The purpose of the present study is to evaluate changes in myocardial resistance over time in STEMI patients, both in the early stage and the subacute phase. Furthermore, the course of such changes and recovery of the microcirculation will be correlated to long-term outcome as assessed by MRI measurements and final infarct size. It is hypothesized that patients can be divided into 3 groups:

A. Patients with an (almost) normal resistance and flow immediately after PPCI

B. Patients with still elevated resistance and decreased flow immediately after PPCI, but (partial) recovery in the next days

C. Patients with elevated resistance and decreased flow immediately after PPCI which do not recover at all.

Study objective

1) To evaluate changes in microvascular resistance of the infarcted area in the first hours after ST-elevation myocardial infarction and during the recovery period (<5 days)
2) To classify patients according to recovery of microvascular resistance
3) To relate (recovery of) microvascular resistance to outcome and preservation of left ventricular function (MRI, echo, clinical FU at 1 yr)

Study design

Propective cohort study, single centre and single arm of 50 STEMI patients

Study burden and risks

There are no specific benefits expected for the patients. The patient just undergoes the best possible state-of-the-art treatment for the disease. Inconvenience and risk associated with participation in this study is minimal.In the acute phase, the patient has to stay for 30 extra minutes in the catheterization laboratory to perform the initial measurements. But that extra period of 30 minutes is applicable to the situation after the stent has been placed, when the patient is mostly relieved from chest pain and feels comfortable again.
In some patients, an observation period of 10-30 minutes in the catheterization laboratory might be desirable anyway for clinical reasons.
The procedure of performing the absolute flow and resistance measurements, carries a neglectable risk. In our experience in more than 300 patients, we have never seen any noticeable complication related to this procedure. The same holds true for the follow-up procedure after three to five days. In the study, only those patients are participating in whom the indication for a second procedure and instrumentation of the coronary artery is necessary anyway (presence of additional coronary stenoses). The study related measurement, only means a prolongation of that procedure by 10-15 minutes. Undergoing echocardiography is routine in the period after myocardial infarction. Undergoing MRI is not routine in all patients, but is completely harmless and without side effects. MRI assessment might have some benefits for the patient on the longer term.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Patients with STEMI * 12 hours and with ST deviation * 5 mm. Who have one or more other lesions mandating FFR or PCI in de following days after PCI of the culprit artery;INCLUSION CRITERIA
* Age between 18 and 75 years
* Presentation within 12 hours after the onset of complaints
* Acute ST-elevation myocardial infarction with a total ST segment deviation *5 mm
* Able to give and understand informed consent
* Culprit lesion in a proximal or mid-segment of one of the major coronary arteries (diameter *2,5 mm), which is stented successfully
* Stable condition after stenting
* One or more additional lesions in one or more different coronary arteries, mandating FFR measurement +/- PPCI during the subacute phase

Exclusion criteria

* Age less than 18 years or more than 75 years
* Cardiogenic shock or pre-shock
* Patients with previous myocardial infarction in the culprit artery or with previous bypass surgery
* Very tortuous or calcified coronary arteries
* Long or complex PCI
* Severe concomitant disease or conditions with a life expectancy of less than 1 year
* Inability to understand and give informed consent
* Known myocardial diseases such as moderate or severe left ventricular hypertrophy or cardiomyopathy
* Pregnancy
* Severe conduction disturbances necessitating implantation of a temporary pacemaker
* Contraindications for MRI (claustrophobia, ferromagnetic metal fragments in the body)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-11-2018
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Rayflow catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-03-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL63404.100.17